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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,489	07/20/2006	Ochayi C. Agboh	978-125	4197

23117 7590 01/20/2010
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EXAMINER

BUCKLEY, AUDREA

ART UNIT	PAPER NUMBER
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1611

MAIL DATE	DELIVERY MODE
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01/20/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,489	Applicant(s) AGBOH ET AL.	
	Examiner AUDREA J. BUCKLEY	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-61 is/are pending in the application.
- 4a) Of the above claim(s) 59-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

Acknowledgement is made of Applicants' claim amendments and remarks filed 10/14/2009. Claims 1-42 are canceled, and new claims 43-61 have been added.

Claims 43-61 are pending.

Newly submitted claims 59-61 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are drawn to a woven or non-woven fibrous article as outlined in Group III of the restriction requirement dated 6/1/2009. As such, the common technical feature, fibers comprising a polymer matrix having at least one metal incorporated therein, cannot be a special technical feature under PCT Rule 13.2. See page 2 of the restriction requirement of 6/1/2009. The finality of this restriction requirement as outlined in the office action of 8/4/2009 is maintained (see page 2 of the non-final rejection of 8/4/2009).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 59-61 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 43-58 are under consideration in the instant Office Action.

Drawings

The drawings were received on 7/20/2006. These drawings are acceptable.

Withdrawn Claim Rejections

The rejection of claims 21, 22, 26-28, 32, and 33 as being anticipated by Burrell et al. (US 2001/0055622) is withdrawn in light of Applicants' amendments to the claims filed 10/14/2009.

The rejection of claims 21, 23-25, and 29-31 under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. is withdrawn in light of Applicants' amendments to the claims filed 9/14/2009.

The rejection of claims 32-34 under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. in view of Qin et al. is withdrawn in light of Applicants' amendments to the claims filed 9/14/2009.

The rejection of claim 35 under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. in view of Dresdner, Jr. et al. is withdrawn in light of Applicants' amendments to the claims filed 9/14/2009.

The rejection of claim 36 under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. and Qin et al. in view of Dresdner, Jr. et al. is withdrawn in light of Applicants' amendments to the claims filed 9/14/2009.

New Grounds of Rejection As Necessitated by Amendments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43, 44, 48-50, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Burrell et al (US 2001/0055622, published Dec. 2001).

Regarding claim 43, Burrell et al. teach antimicrobial materials which provide an effective and sustainable antimicrobial effect through the implementation of antimicrobial metals into a polymeric matrix, among other formulations (page 1, column 1, [0001], in particular; see also, page 5, column 2, [0078]). In particular, Example 4 illustrates a silver-coated chitosan (natural polymer) powder (see page 7, column 2, [0109]-[0113]) having requisite nanoparticles of the metal (see page 5, column 1, [0075]). Burrell et al. also generally disclose a polymer matrix identity which is comprised of synthetic bioabsorbable polymers or of naturally derived polymers (page 1, [0010]-[0013]). Further, with regard to claim 43, which is a product-by-process limitation, the examiner directs applicant's attention to MPEP 2113: even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product by process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

As to claim 44, Burrell et al. teach a formulation into which the antimicrobial metals can be in the form of a continuous coating (page 1, column 2, [0020]). As to claim 48, Burrell et al. teach metal nanoparticles which exhibit antimicrobial properties (page 1, column 2, [0019]). As to claim 49, Burrell et al. teach antimicrobial metal identities as Ag, Au, Pt, Pd, Ir, Sn, Cu, Sb, Bi, Zn, or alloys or compounds thereof (page 9, claim 14). As to claim 50, silver is listed as a

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metal identity comprising the nanocrystalline coating or powder disclosed (page 9, claim 14). As to claim 54, alginate is named among the polymers acceptable for use in the preferred embodiments (page 1, [0013]; see also Example 2).

Since the content and limitations of instant claims 43, 44, 48-50, and 54 are all taught in the Burrell et al. reference, these claims are rejected as being anticipated by Burrell et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. (US 200110055622, published Dec. 2001).

The teachings of Burrell et al. are delineated above, particularly as they apply to claims 43, 44, 48-50, and 54.

Regarding claims 45-47, Burrell et al. do not specify that the particular embodiment implements metal nanoparticles of the size limitations instantly claimed; it is for this reason that these claims are rejected under obviousness. Similarly, regarding claims 51-53, Burrell et al. do not teach the instantly claimed fiber diameter.

Regarding claim 45, which limits the metal nanoparticles to those having a size less than 500 nm, Burrell et al. teach metal nanoparticles to those having a size preferably less than 100 nm (page 1, column 2, [0020]). As to claim 46, Burrell et al. teach that the antimicrobial metals are present in particulate or crystalline size of less than 100 nm (page 1, column 2, [0020]-[0021]). As to claim 47, which limits the metal particle size to a value between 20 and 100 nm, Burrell et al. previously teach metal particles less than 100 nm and most preferably less than 20 nm (page 1, column 2, [0020]-[0021]). Although this prior teaching differs from that of the instant claim with respect to the desirable particle size minimum, one of ordinary skill in the art at the time the invention was made would have been motivated to perform routine optimization procedure about the previously taught size limitation values. MPEP 2144.05 addresses as follows the obviousness of overlapping ranges taught in the prior art:

In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257,

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191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

A prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness. In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003), See also In re Harris, 409 F.3d 1339, 74 USPQ2d 1951 (Fed. Cir. 2005),

Regarding claim 51 which limits the fiber diameter, Burrell et al. teach analogous art which limits a polymer film coating containing antimicrobial metals to a thickness of 500 microns (page 9, claim 7). Also, Burrell et al. teach coating fibers as an acceptable embodiment of the invention (page 5, [0078]). Likewise and as to claims 52 and 53, Burrell et al. teach an antimicrobial coating thickness of preferably less than 500 nm and very fine grained, with a powder particle size of preferably less than 100 micrometers or preferably less than 40 micrometers (page 1, [0021]) for powder formulations analogous to the art instantly disclosed. Although this prior teaching differs from that of the instant claim with respect to the fiber diameter size limitations, one of ordinary skill in the art at the time the invention was made would have been motivated to perform routine optimization procedure about the previously taught limitation values. See MPEP 2144.05 for routine optimization procedure as it relates to patentability.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize the features (i.e., antimicrobial metal identity, polymer matrix identity, nanoparticle size, fiber size, etc.) disclosed by Burrell et al. in the endeavor of antimicrobial bioabsorbable materials. The skilled artisan would have been motivated to

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combine known preferred features with one another in order to continue the known success of these materials comprising a polymer matrix and antimicrobial, nanoparticulate metal inclusion. For example, metal particles of the nano scale were known to demonstrate efficacy as a coating into or onto a polymer scaffold, therefore the skilled artisan would have been motivated to implement metal particles of the metal identity and recommended particle size as taught by Burrell et al., and the skilled artisan would have expected continued success for doing so, particularly since the instant invention is drawn to solve the same problems and applications as the prior teaching of Burrell et al.

Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. (US 2001/0055622, published Dec. 2001) in view of Qin et al. (WO02/36866, May 2002).

The teachings of Burrell et al. are delineated above. Further, Burrell et al. disclose a polymer matrix identity which can be comprised of synthetic bioabsorbable polymers or of naturally derived polymers (page 1, [0010]-[0013]). As to claim 55, alginate is named among the polymers acceptable for use in the preferred embodiments (page 1, [0013]). Regarding claims 55 and 56, Burrell et al. do not teach a quantitative limitation of silver presence in the polymer matrix comprising alginate.

Nonetheless, Qin et al. teach polysaccharide fibers having antimicrobial properties wherein these fibers comprise alginate as well as antimicrobial metal containing particles which are present in a concentration between 0.1 and 2% w/w (page 21, claims 1 and 7).

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It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to implement the quantitative anti-microbial silver- containing agent into the bioabsorbable materials as disclosed by Qin et al. into an analogous formulation such as that taught by Burrell et al. Further, one of ordinary skill in the art reasonably would have expected continued success from this implementation, particularly since both analogous teachings of Burrell et al. and Qin et al. had independently demonstrated prior success in the art.

Claims 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. (US 2001/0055622) and Qin et al. (WO02/36866) as applied to claims 43-54 above, and further in view of Spence (US 4,226,232, Oct. 1980).

The teachings of Burrell et al. and Qin et al. are delineated above. Specifically, Qin et al. teach polysaccharide fibers having antimicrobial properties wherein these fibers comprise antimicrobial metal particles present in a concentration between 0.1 and 2% w/w (page 21, claims 1 and 7).

Neither Burrell et al. nor Qin et al. explicitly teach polyacrylonitrile as the synthetic polymer identity.

Spence teaches wound dressings having an absorbent graft copolymer which gives structure to the dressings. Additional components such as local anesthetics, hormonal compounds, enzymes, antibacterial agents, antifungal agents, or silicone compounds can also be incorporated into the copolymer (see abstract, in particular). Specifically, starch-polyacrylonitrile graft copolymers are the preferred wound dressing material (see column 2, lines 35-39).

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It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the silver metal in the a quantity as taught by Qin et al., a range overlapping with that instantly claimed, into a known wound dressing material including the polyacrylonitrile material taught by Spence. The skilled artisan would have been motivated to do so since the article taught by Spence had demonstrated prior success and since Spence suggests incorporating active agents such as antibacterial agents into the wound dressing material.

Response to Arguments

Applicants' arguments have been fully considered but are moot in light of the amendments to the claims submitted 10/14/2009.

Applicant argues that there is no teaching in Burrell of extrusion or sonication giving the claims clear novelty. As addressed above, product-by-process limitations do not carry patentable weight, and the relevance of the Burrell reference is maintained.

Applicant states that Burrell teaches away from the retention of the nanoparticles in polymer matrices. It is, however, maintained, that Burrell teaches the incorporation of the metal particles into various polymers. Furthermore, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 371 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). Similarly, the instant disclosure does not teach unexpected results in contrast with Burrell's disclosure. MPEP 2123 addresses the validity of a rejection over prior art's disclosure as follows:

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Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non preferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). “A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.” *In re Gurley*, 27 F.2d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have “relatively actable dimensional stability” and “some degree of flexibility,” but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant’s argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since “Gurley asserted no discovery beyond what was known in the art.” 27 F.3d at 554, 31 USPQ2d at 1132).

Burrell teach the incorporation of nanocrystalline powders (metals) into a bioabsorbable substrate where the powders may be layered onto the bioabsorbable substrate as a coating, mechanically mixed within the fibers, or impregnated into the bioabsorbable substrate.

Alternatively, the nanocrystalline powder may be incorporated into a polymeric, ceramic, metallic matrix, or other matrices to be used as a material for the manufacture of bioabsorbable substrates, medical devices, etc. (see paragraph [0078]). Based on this teaching, the skilled artisan at the time of the invention would have had a reasonable expectation of success.

Additionally, Applicants present that the teachings of Qin totally conflict with the aims of the instant invention on account of the sonication step. Please see discussion regarding product-by-process limitations as outlined above. It is maintained that the teachings of Burrell et al. and Qin et al. would have been considered analogous art by the skilled artisan.

Applicants dispute the addition of the Dresdner document reference for the same reason as disputing that of Qin. It is maintained that the teachings of Burrell et al., Qin et al., and

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Dresdner et al. would have been considered analogous art by the skilled artisan, however this is moot since the Dresdner et al. reference has been withdrawn in view of Applicants' amendments to the claims as presented 10/14/2009.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/AJB/

/David J Blanchard/
Primary Examiner, Art Unit 1643